II. REMARKS

Claims 1 to 50 are currently pending in the subject application. New claims 51 to 67, which are directed towards alternative embodiments of the present invention, are presented herein for prosecution. Support for the new claims can be found throughout the specification, and as particularly identified in the Table of Exemplary Support for New Claims that follows:

Table of Exemplary Support for New Claims

51.	A dry reagent lateral flow strip assay device	A "dry reagent assay device" is recited at 1:17. The "lateral flow" is recited at 15:12.
	for detecting at least one analyte in a test sample within a pre-determined range of analyte concentration using a porous member capable of being traversed by the sample comprising:	Detection of "analytes in a sample" is recited at 3:8. The "pre-determined range of each selected analyte" is recited at 8:24-25. The term "test sample" is recited at 19:13. The "porous member capable of being traversed by the sample" is recited at 9:22-23.
	a) a sample application zone on the porous member having diffusively immobilized therewith a labeled indicator reagent;	The porous member includes a zone that "receives and contacts the sample with a labeled indicator reagent diffusively immobilized on the porous member." (9:24-25.) As discussed on page 22:21-22, the labeled indicator reagent as exemplified by a "particle-linked antigen" may be located "at or near the application site".
	b) at least one test zone having non-diffusively bound thereto a first reagent that forms a first reaction product and a corresponding test zone detectable response inversely proportional to the analyte concentration;	The test zone is described at 8:4-13.
	c) at least one reference zone having non-diffusively	The reference zone is

	bound thereto a second reagent that forms a second reaction product and a corresponding reference zone detectable response directly proportional to the analyte concentration;	described at 8:14-22.
	wherein the sample application zone, the test zone and the reference zone are in fluid communication with one another through the porous member; and	The device "includes a porous member capable of being traversed by the sample." (9:21-23.)
	wherein the test zone detectable response plus the reaction zone detectable response equal a total detectable response that is substantially constant for the pre-determined range of analyte concentration.	The assay results in establishing "a substantially constant total detectable response for a pre-determined range of each selected analyte." (8:23-25 and 15:17-24.)
52.	The assay device of claim 52, wherein the porous member further comprises a bibulous solid phase material.	The "bibulous....solid phase materials" are described at 20:11.
53.	The assay device of claim 52, wherein the porous member further comprises fiberglass, cellulose or nylon.	The substances (fiberglass, cellulose and nylon) are described at 20:13.
54.	The assay device of claim 51 for detecting multiple analytes in a test sample, further comprising more than one test zone, each corresponding to an analyte.	The multiple analyte assay configuration is described at 28:14 to 29:15.
55.	The assay device of claim 51, wherein the porous member further comprises more than one bibulous material , wherein the sample application zone, the test zone and the reference zone are in fluid communication therethrough.	A device with two or more "separate bibulous material[s]" is described on 31:9-14, which also describes that "each zone is in fluid communication with adjacent zones".
56.	The assay device of claim 51, further comprising one or more reagents diffusively or non-diffusively bound to the porous member selected from the group consisting of: antibodies, antigens, enzymes, substrates, small molecules, proteins, viral lysate, bacterial lysate, receptors, sugars, carbohydrates, polymers and detergents.	These additional reagents are recited at 32:3-8.
57.	The assay device of claim 51, further comprising a sample filtration member.	Sample filtration is described at 33:25 to 34:8, and is depicted in Figure 5.
58.	The assay device of claim 51, wherein the labeled indicator reagent is a particle-linked antigen or a particle linked antibody.	The use of a "particle-linked antigen" as the indicator reagent in a competitive assay is described at 21:22-24. The use of a "particle-linked antibody" as the indicator

		reagent in an inhibition assay is described at 23:13-16.
59.	The assay device of claim 51, wherein the first reagent is an antibody or an antigen.	The use of an antibody as the first reagent in a competitive assay is described at 22:1-3. The use of an antigen as the first reagent in an inhibition assay is described at 23:18-20.
60.	The assay device of claim 51, wherein the second reagent is an antibody that binds to the labeled indicator reagent to form the second reaction product.	The second reagent is further described as a "first member of a specific binding pair" in both the competitive assay format (at 23:9) and the inhibition assay format (at 24:21-22). In one embodiment, "[t]he antibody is a first member of a specific binding pair capable of binding to a second member of the specific binding pair", which is part of the diffusively bound labeled indicator reagent, as further described at 11:3-14.
61.	A method of performing a dry reagent lateral flow strip assay for detecting at least one analyte in a test sample within a pre-determined range of analyte concentration comprising the steps of:	See claim 51.
	a) providing a porous member capable of being traversed by the sample, wherein the porous member further comprises: i) a sample application zone on the porous member having diffusively immobilized therewith a labeled indicator reagent; ii) at least one test zone having non-diffusively bound thereto a first reagent that forms a first reaction product and a corresponding test zone detectable response inversely proportional to the analyte concentration; and iii) at least one reference zone having non-diffusively bound thereto a second reagent that forms a second reaction product and a corresponding reference zone detectable response directly proportional to the analyte concentration;	See claim 51.

	b) contacting the sample application zone with the sample; and	See claim 51.
	c) detecting the test zone detectable response and the reagent zone detectable response, wherein the test zone detectable response plus the reaction zone detectable response equal a total detectable response that is substantially constant for the pre-determined range of analyte concentration.	See claim 51.
62.	The method of claim 61, wherein the test sample is derived from whole blood, whole blood components, ascites, urine, sweat, milk, synovial fluid, peritoneal fluid, amniotic fluid or cerebrospinal.	These exemplary samples are described at 19:13-15.
63.	The method of claim 61, wherein the analyte is an antigenic substance selected from the group consisting of: a protein, a peptide, an amino acid, a hormone, a steroid, a vitamin, a drug, a bacterium, and a virus.	These exemplary analytes are recited at 17:20-24.
64.	The method of claim 61, wherein the total detectable response is a form of electrical conductance, reflectance of a characteristic light wavelength, or absorption of a characteristic light wavelength.	These exemplary responses are recited at 26:12-14.
65.	The method of claim 61, wherein the porous member further comprises a bibulous material with proximal and distal ends.	"In a preferred embodiment, the present dry reagent assay device uses a lateral flow bibulous material with proximal and distal ends." (20:19-21)
66.	A system for performing a dry reagent lateral flow strip assay for detecting at least one analyte in a test sample within a pre-determined range of analyte concentration comprising:	See claim 51.
	a) a porous member capable of being traversed by the sample, wherein the porous member further comprises: i) a sample application zone on the porous member having diffusively immobilized therewith a labeled indicator reagent; ii) at least one test zone having non-diffusively bound thereto a first reagent that forms a first reaction product and a corresponding test zone detectable response inversely proportional to the analyte concentration; and iii) at least one reference zone having non-diffusively bound thereto a second reagent that forms a second reaction product and a corresponding reference zone detectable response directly proportional to the analyte concentration; and	See claim 51.
	b) an assay instrument that measures the test zone	The use of an instrument to

	detectable response and the reference zone detectable response	measure the response is described at 25:24 to 26:6 and 48:11-13.
67.	The system of claim 66, wherein the assay instrument further comprises a reflectance meter or a transmission meter.	These exemplary instruments are recited at 26:3.

III. CONCLUSION

Applicants contend that all pending claims in this case are in condition for allowance. The examiner is cordially invited to telephone the undersigned at 619-446-5622 should she/he believe that a discussion could resolve any outstanding issues.

Respectfully submitted,

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